NOV - 8 2000

K002966

Ocu-Ease Optical Products, Inc.
510(k) Premarket Notification
Ocu-Flex-49 Spherical, Toric, Aspherical and Toric Aspherical (hioxifilcon B) Soft Contact Lenses for Daily Wear

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Ocu-Ease
Optical Products, Inc.

629 Tennent Avenue
Pinole, California 94564
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510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Assigned 510(k) Number: _____

Applicant Information:

Date Prepared:	September 1, 2000
Name:	Ocu-Ease Optical Products, Inc.
Address:	629 Tennent Avenue Pinole CA. 94564
Contact Person:	Charles R. Vermette President
Phone/Fax Number:	Phone: (510)724-0384 Fax: (510)724-4842

Device Information:

Device Classification:	Class II
Classification Number:	LPL
Classification Name:	Lenses, Soft Contact, Daily Wear
Device Trade Name:	Ocu-Flex-49 Spherical, Toric, Aspherical and Toric Aspherical (hioxifilcon B) Soft Contact Lenses for Daily Wear (Clear and Blue Visibility Tint, lathe-cut)

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SUMMARY OF SAFETY AND EFFECTIVENESS
(continued)

Equivalent Devices:

The Ocu-Flex-49 Spherical, Toric, Aspherical and Toric Aspherical (hioxifilcon B) Soft Contact Lenses for Daily Wear is substantially equivalent to the predicate device(s) identified below in terms of intended use and design.

Predicate Device:

Ocu-Flex-53 (ocufilcon B) Soft (Hydrophilic) Contact Lens for Daily Wear
PMA #P820051
Manufactured By: Ocu-Ease Optical Products, Inc.

UCL-55, Toric, Multifocal and Toric Multifocal (ocufilcon C) Soft Contact Lens for Daily Wear
PMA #P920008
Manufactured by: United Contact Lens

Device Description:

The Ocu-Flex-49 Spherical, Toric, Aspherical and Toric Aspherical (hioxifilcon B) Soft Contact Lenses are fabricated from hioxifilcon B, which in the dry (unhydrated) state may be machined and polished. The hydrophilic nature of this material allows the lens to become soft and pliable when immersed in an aqueous solution.

In the hydrated state, the lens conforms to the curvature of the eye covering the cornea and extending slightly beyond the limbus forming a colorless, transparent optical surface. The hydrophilic properties of the lens require that it be maintained in a fully hydrated state in a solution compatible with the eye. If the lens dries out, it will become hard and appear somewhat warped however, it will return to its proper configuration when completely rehydrated in the proper storage solution.

The non-ionic lens material (hioxifilcon B) is a hydrophilic co-polymer of 2,3-dihydroxypropyl methacrylate and 2-hydroxyethyl-methacrylate. When fully hydrated in a 0.9% sodium chloride solution, the lens is 49% water by weight. In

SUMMARY OF SAFETY AND EFFECTIVENESS
(continued)

that fully hydrated state the lens is soft and readily wet by saline and aqueous solution.

The Ocu-Flex-49 Spherical, Toric, Aspherical and Toric Aspherical (hioxifilcon B) Soft Contact Lenses are available as a spherical, toric, aspheric and toric aspheric design.

The physical properties of the lens are:

Refractive Index	1.42
Light Transmission	greater than 95% T
Specific Gravity	1.30
Water Content	49%
Color Pigment Name	Phthalocyanine Blue
Oxygen Permeability	15×10^{-11} (cm^2 /sec)(ml O_2 / ml x mm Hg@35°C),(revised Fatt method).

Intended Use:

The Ocu-Flex-49 Spherical, Toric, Aspherical and Toric Aspherical (hioxifilcon B) Soft Contact Lenses are indicated for daily wear for the correction of refractive ametropia (myopia, hyperopia and astigmatism) in not-aphakic persons with non-diseased eyes.

The Ocu-Flex-49 Spherical (hioxifilcon B) Soft Contact Lens is indicated for daily wear for the correction of visual acuity in aphakic or not-aphakic persons with non-diseased eyes that are nearsighted (myopic) or farsighted (hyperopic) and may exhibit astigmatism of 1.50D or less that does not interfere with visual acuity.

The Ocu-Flex-49 Toric (hioxifilcon B) Soft Contact Lens is indicated for daily wear for the correction of visual acuity in aphakic or not-aphakic persons with non-diseased eyes that are myopic or hyperopic and is intended to correct astigmatism of 4.50D or less that does not interfere with visual acuity.

The Ocu-Flex-49 Aspherical (hioxifilcon B) Soft Contact Lens is indicated for daily wear for the correction of visual acuity in aphakic or not-aphakic persons with non-diseased eyes that are myopic, or hyperopic, and/or presbyopic, and which may exhibit astigmatism of up to 1.50D or less that does not interfere with visual acuity.

Ocu-Ease Optical Products, Inc.

510(k) Premarket Notification

Ocu-Flex-49 Spherical, Toric, Aspherical and Toric Aspherical (hioxifilcon B) Soft Contact Lenses for Daily Wear

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SUMMARY OF SAFETY AND EFFECTIVENESS
(continued)

The Ocu-Flex-49 Toric Aspherical (hioxifilcon B) Soft Contact Lens is indicated for daily wear for the correct of visual acuity in aphakic or not-aphakic persons with non-diseased eyes that are myopic, or hyperopic, and/or presbyopic and is intended to correct astigmatism of 4.50D or less that does not interfere with visual acuity.

The lens may be disinfected with either a heat (thermal) or chemical (not heat) disinfection system.

Substantial Equivalence:

The new device will be manufactured according to specified process controls and a Quality Management System certified to CGMP guidelines currently in place. The device will undergo manufacturing, packaging and sterilization procedures similar to devices currently manufactured, marketed and distributed by Ocu-Ease Optical Products, Inc. The established safety profile (pre-clinical toxicology and manufacturing/chemistry data) of the device is equivalent to the BENZ-G 3X, 510(k) K964528. Being similar with respect to indications for use, materials, physical construction and safety and effectiveness to the predicate devices, this meets the requirements per section 510(k) of the act regarding substantial equivalence and *does not raise different questions of safety and effectiveness than the predicate devices identified above.*

The following matrix illustrates that the production method, lens function and material of the Ocu-Flex-49 Spherical, Toric, Aspherical and Toric Aspherical (hioxifilcon B) Soft Contact Lenses for Daily Wear is substantially equivalent to the predicate device. In addition, the water content, polymer, Dk value, refractive index, specific gravity, and light transmission are as well substantially equivalent to the predicate device.

Signed: Charles R. Vermette Date: 09/20/2000
Charles R. Vermette, President

Ocu-Ease Optical Products, Inc.
510(k) Premarket Notification
Ocu-Flex-49 Spherical, Toric, Aspherical and Toric Aspherical (hioxifilcon B) Soft Contact Lenses for Daily Wear

SUMMARY OF SAFETY AND EFFECTIVENESS
(continued)

Substantial Equivalence Matrix

	Characteristic	Ocu-Flex-49 Spherical, Toric, Aspherical and Toric Aspherical (hioxifilcon B) Soft Contact Lenses	*Predicate Device:* Ocu-Flex-53 (ocufilcon B) Soft Contact Lens	*Predicate Device:* UCL-55, Toric, Multifocal & Toric Multifocal (ocufilcon C) Soft Contact Lens
1.)	**PRODUCTION METHOD**	Lathe-cut	Lathe-cut	Lathe-cut
2.)	**LENS FUNCTION**	Refractive medium that focuses light rays from near and distant objects on the retina, while compensating for refractive error	Refractive medium that focuses light rays from near and distant objects on the retina, while compensating for refractive error	Refractive medium that focuses light rays from near and distant objects on the retina, while compensating for refractive error
3.)	**INDICATION**	Correction of visual acuity in aphakic and not-aphakic persons with non-diseased eyes with myopia, hyperopia and astigmatism	Correction of visual acuity in aphakic and not-aphakic persons with non-diseased eyes with myopia, hyperopia and astigmatism	Correction of visual acuity in aphakic and not-aphakic persons with non-diseased eyes with myopia, hyperopia and astigmatism
3.)	**MATERIAL**	hydrophilic (hioxifilcon B)	hydrophilic (ocufilcon B)	hydrophilic (ocufilcon C)
4.)	**WATER CONTENT**	49%	53%	55%
5.)	**Dk Value**	15	18.1	18.8

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 8 2000

Mr. Charles R. Vermette
President
Ocu-Ease Optical Products, Inc.
629 Tennent Avenue
Pinole, CA 94564

Re: K002966
Trade Name: Ocu-Flex-49 Spherical, Toric, Aspherical and Toric Aspherical (hioxifilcon B) Soft Contact Lenses for Daily Wear (clear and tinted).
Regulatory Class: II
Product Code: LPL
Dated: September 20, 2000
Received: September 22, 2000

Dear Mr. Vermette:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-6413. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

A. Ralph Rosenthal

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Ocu-Ease Optical Products, Inc.
510(k) Premarket Notification
Ocu-Flex-49 Spherical, Toric, Aspherical and Toric Aspherical (hioxifilcon B) Soft Contact Lenses for Daily Wear

INDICATIONS FOR USE STATEMENT

Device Name: **Ocu-Flex-49 Spherical, Toric, Aspherical and Toric Aspherical (hioxifilcon B) Soft Contact Lenses (Clear & Blue Visibility Tint, Lathe-cut from Lens Blank)**

INDICATIONS FOR USE:

The Ocu-Flex-49 Spherical, Toric, Aspherical and Toric Aspherical (hioxifilcon B) Soft Contact Lenses are indicated for daily wear for the correction of refractive ametropia (myopia, hyperopia and astigmatism) in not-aphakic persons with non-diseased eyes.

The Ocu-Flex-49 Spherical (hioxifilcon B) Soft Contact Lens is indicated for daily wear for the correction of visual acuity in aphakic or not-aphakic persons with non-diseased eyes that are nearsighted (myopic) or farsighted (hyperopic) and may exhibit astigmatism of 1.50D or less that does not interfere with visual acuity.

The Ocu-Flex-49 Toric (hioxifilcon B) Soft Contact Lens is indicated for daily wear for the correction of visual acuity in aphakic or not-aphakic persons with non-diseased eyes that are myopic or hyperopic and is intended to correct astigmatism of 4.50D or less that does not interfere with visual acuity.

The Ocu-Flex-49 Aspherical (hioxifilcon B) Soft Contact Lens is indicated for daily wear for the correction of visual acuity in aphakic or not-aphakic persons with non-diseased eyes that are myopic, or hyperopic, and/or presbyopic, and which may exhibit astigmatism of up to 1.50D or less that does not interfere with visual acuity.

The Ocu-Flex-49 Toric Aspherical (hioxifilcon B) Soft Contact Lens is indicated for daily wear for the correct of visual acuity in aphakic or not-aphakic persons with non-diseased eyes that are myopic, or hyperopic, and/or presbyopic and is intended to correct astigmatism of 4.50D or less that does not interfere with visual acuity.

The lens may be disinfected with either a heat (thermal) or chemical (not heat) disinfection system.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE) Division of Ophthalmic Devices

Prescription Use X (Per 21 CFR 801.109) OR Over-The-Counter Use_____

(Optional Format 1-2-96)

Daniel W. C. Brown, Ph.D.

(Division Sign-Off)
Division of Ophthalmic Devices

510(k) Number K002966